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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/674,817	11/06/2000	Horst Loerz	514413-3849	5231

20999 7590 07/01/2003

FROMMER LAWRENCE & HAUG  
745 FIFTH AVENUE- 10TH FL.  
NEW YORK, NY 10151

EXAMINER
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BAUM, STUART F

ART UNIT	PAPER NUMBER
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1638

17

DATE MAILED: 07/01/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/674,817

Applicant(s)

LOERZ ET AL.

Examiner

Stuart F. Baum

Art Unit

1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 21 April 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 24-46 and 51-53 is/are pending in the application.
- 4a) Of the above claim(s) 30,33,34 and 51-53 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 24-29,31,32 and 35-46 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 16.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

**DETAILED ACTION**

1. The amendment filed 4/21/2003 has been entered.

Claims 24-46 and 51-53 are pending.

Claims 47-50 have been canceled.

Claims 30, 33, 34, and 51-53 have been withdrawn from consideration because the claims are drawn to non-elected inventions.

Claims 24, 27, 29, 32, and 45 have been amended.

2. Claims 24-29, 31-32, and 35-46 are examined in the present office action.

3. This application contains claims 30, 33, 34, and 51-53 drawn to an invention nonelected with traverse in Paper No. 12. A complete reply to the final rejection must include cancelation of nonelected claims (37 CFR 1.144) See MPEP § 821.01.

4. Rejections and objections not set forth below are withdrawn.

5. The text of those sections of Title 35, U.S. Code not included in this office action can be found in a prior office action.

***Written Description***

6. Claims 24-29, 31-32, and 35-46 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the

Art Unit: 1638

application was filed, had possession of the claimed invention. This rejection is maintained for the reasons of record set forth in the Official action mailed 10/23/2002. Applicant's arguments filed 4/21/2003 have been fully considered but they are not persuasive.

Applicants contend that the amino acid sequence recited in claim 24 provides a description of the structure and that molecules that hybridize to or have a degree of identity with the recited sequences meets the requirements of § 112, first paragraph (page 7, 1<sup>st</sup> sentence). Applicants further contend that the specification teaches the function of isoamylases along with references describing isoamylases from maize and potato. In short, Applicant contends that isoamylases are debranching enzymes that are involved in starch metabolism and fall within the scope of their claims. Applicants also contend that a functional description may be sufficient to satisfy the written description requirement. Applicants believe that they have satisfied the written description requirement by disclosing the entire sequence of SEQ ID NO:2 and including in the specification a description of the function of the claimed invention. Lastly, Applicants believe that they are entitled to a genus of isoamylase enzymes.

The Office asserts that for claims drawn to an isolated sequence, a disclosure of that sequence in the form of a SEQ ID NO sufficiently satisfies the written description requirement. But, for claims drawn to sequences that exhibit less than 100% sequence identity to the claimed SEQ ID NO, Applicants are required to describe the functional and/or characteristic domains of the protein and to disclose nucleic acid sequences that encode the functional or characteristic domains. A description of the function of the enzyme does not satisfy the written description requirement for claims drawn to sequences exhibiting less than 100% sequence identity when compared to a specific SEQ ID NO. Applicants are not entitled to a genus when they only

Art Unit: 1638

disclose one species. This is especially true given Applicants own teachings that describe isoamylases that utilize different substrates than the one that is acted upon by Applicants SEQ ID NO:3 (page 3, lines 1-18). Simply describing that a claimed genus uses as a particular molecule as a substrate does not entitle Applicant to claim an entire genus.

### *Enablement*

7. Claims 24-29, 31-32, and 35-46 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This rejection is maintained for the reasons of record set forth in the Official action mailed 10/23/2002. Applicant's arguments filed 4/21/2003 have been fully considered but they are not persuasive.

Applicants contend that they have taught stringent hybridization conditions as disclosed on page 5, line 10 of the specification. Applicants also contend that they have taught how to isolate and characterize cDNA molecules encoding wheat isoamylase. Lastly, Applicants contend that they have sufficiently disclosed how to isolate the claimed nucleic acid molecules such that undue experimentation is not required to practice the claimed invention.

The Office asserts that Applicants have not taught stringent hybridization conditions on page 5, line 10, but rather disclosed a general recipe for hybridization including a range of temperatures that can be used. Applicants have not specifically taught a stringent hybridization condition that can be used to isolate the claimed invention from the multitude of non-exemplified sequences isolated from the multitude of plants that are encompassed in Applicants claims. In

Art Unit: 1638

addition, Applicants have only taught how to isolate a wheat isoamylase and have not taught how to isolate the homologous isoamylase from the multitude of plants encompassed in Applicants claims. Given the reasons stated above and the reasons stated in the Official office action mailed 10/23/2002, it would require undue experimentation to make and/or use the broadly claimed invention.

*35 USC § 102(e)*

8. Claims 24-28, 31-32, 35-42, and 45 remain rejected under 35 U.S.C. 102(e) as being anticipated by Kossmann et al (July 1997, U.S. Patent 6,130,367). This rejection is maintained for the reasons of record set forth in the Official action mailed 10/23/2002. Applicant's arguments filed 4/21/2003 have been fully considered but they are not persuasive.

Applicants contend that the invention of Kossman et al relates to a soluble starch synthase and a starch granule-bound starch synthase from potato, which are completely different enzymes than the wheat isoamylase of Applicant's invention. Applicants contend the the Kossman et al nucleic acid sequences would not hybridize with the claimed sequences.

The Office contends that given the broadly defined hybridization conditions, i.e., wash temperature 45-70<sup>0</sup>C and absence of time; and the lack of definition for a wheat isoamylase, Applicants broadly claimed sequences would indeed hybridize with the sequences of Kossman et al.

*35 USC § 103*

9. Claims 24-28, 31-32, and 35-45 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Kossmann et al (July 1997, U.S. Patent 6,130,367) taken with Vasil et al (April 1995, U.S. Patent 5,405,765). This rejection is maintained for the reasons of record set forth in the Official action mailed 10/23/2002. Applicant's arguments filed 4/21/2003 have been fully considered but they are not persuasive.

Applicants contend that Kossmann et al do not teach or suggest nucleic acid molecules that would hybridize under stringent conditions, to those of the present application. In addition, the methods of Vasil et al, when combined with the teachings of Kossmann et al would not result in the present invention.

The Office contends that given the broadly defined hybridization conditions, i.e., wash temperature 45-70<sup>0</sup>C and absence of time; and the lack of definition for a wheat isoamylase, Applicants broadly claimed sequences would indeed hybridize with the sequences of Kossmann et al. The sequences of Kossmann et al., combined with the teachings of Vasil et al would produce Applicant's broadly claimed invention.

10. Claims 24-28, 31-32, 35-42, and 45-46 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Kossmann et al (July 1997, U.S. Patent 6,130,367) taken with Baltensperger et al (April 1996, U.S. Patent RE. 35,202). This rejection is maintained for the reasons of record set forth in the Official action mailed 10/23/2002. Applicant's arguments filed 4/21/2003 have been fully considered but they are not persuasive.

Art Unit: 1638

Applicants contend that Kossman et al do not teach or suggest nucleic acid molecules that would hybridize under stringent conditions, to those of the present application. In addition, the methods of Baltensperger et al, when combined with the teachings of Kossman et al would not result in the present invention.

The Office contends that given the broadly defined hybridization conditions, i.e., wash temperature 45-70°C and absence of time; and the lack of definition for a wheat isoamylase, Applicants broadly claimed sequences would indeed hybridize with the sequences of Kossman et al. The sequences of Kossman et al., combined with the teachings of Baltensperger et al would produce Applicant's broadly claimed invention.

11. No claims are allowed.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stuart Baum whose telephone number is (703) 305-6997. The examiner can normally be reached on Monday-Friday 8:30AM – 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (703) 306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 or (703) 305-3014 for regular communications.

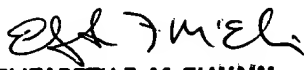


Art Unit: 1638

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist, who may be contacted at 308-0196.

Stuart F. Baum Ph.D.

June 25, 2003

  
ELIZABETH F. McELWAIN  
PRIMARY EXAMINER  
GROUP 1600